Journal of Forensic and Legal Medicine 19 (2012) 437–441

Contents lists available at SciVerse ScienceDirect

Journal of Forensic and Legal Medicine

journal homepage: www.elsevier.com/locate/jflm

Medical error reporting should it be mandatory in Scotland?

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ARTICLE INFO

Article history:
Received 14 September 2011
Received in revised form
19 February 2012
Accepted 21 April 2012
Available online 16 May 2012

Keywords:
Mandatory reporting
Voluntary reporting
Scotland
Medical ethics
Litigation
England

ABSTRACT

Healthcare professionals have an ethical and professional responsibility to report medical errors. Doctors in particular are duty bound to consider the best interests of their patients and 'do no harm'. Medical errors are rarely due to individual human error but are often systems based and in many cases are avoidable. Reporting and learning from medical errors improves the safety of patients.

It has been over ten years since the reports *To Err Is Human* and *An Organisation* with a *Memory* highlighted the scale of preventable medical errors. These statistics, stimulated worldwide health organisations to prioritise patient safety. Both reports recommended the implementation of a voluntary near-miss reporting system and mandatory reporting of serious adverse incidents that had caused physical or psychological harm or death. Currently in Scotland reporting of all errors is voluntary and there is no sharing of information between Health Boards. Studies have demonstrated failings of the voluntary system and preventable medical errors are still occurring in Scotland.

The UK Government in England as of April 2010 has changed the voluntary system of reporting serious adverse events to a mandatory obligation. Failure to report may result in a fine of £4000 to the Trust.

Patient groups wish the system in Scotland to become mandatory with public disclosure. This would ensure openness, honesty and autonomy for patients. This article reviews the controversial issue of mandatory reporting and whether or not this would improve the safety of patients. In conclusion, Scotland would benefit from mandatory reporting of serious adverse events and voluntary near-miss reporting.

1. Introduction

The National Health Service in the UK successfully treats over one million patients each day.[1] However, today's healthcare involves a complex combination of medical technology, medication and medical professionals with different specialised skills and knowledge. Unfortunately, errors do occur and at a great cost to patients. Healthcare staff by the very nature of being human are susceptible to medical error. To improve patient safety, healthcare professionals must identify these errors and consider what lessons might be learned by significant event audit through effective clinical governance. Consideration requires to be given on the benefit of reporting of errors and whether this should be mandatory.

In 1999 The Institute of Medicine in the United States of America released the report *To Err Is Human*, which estimated that more than one million preventable adverse events occur there each year.[2] The report also calculated that up to 98,000 American people die each year as a result of medical errors which could have been prevented.[2] These include incidents such as incorrect blood transfusions, mistaken patient identification and surgery on the wrong side. One of the report's recommendations to improve patient safety was to establish an error reporting system that was nationwide and non-punitive. It recommended a voluntary 'near-miss' system for quality improvement and a mandatory system for serious adverse events that had caused harm or death.

A year later (2000) in the United Kingdom the Chief Medical Officer, Sir Liam Donaldson, released his report *An Organisation with a Memory* in which he proposed "the creation of a new national system for reporting and analysing adverse healthcare events, to make sure that key lessons are identified and learned".[3] It also advised that such a reporting system should be mandatory.[3] This would ideally change the NHS into an organisation with memory that learned from its mistakes.

The Department of Health released its policy document *Building a Safer NHS*[4] in 2001, which detailed how the recommendations of *An Organisation with a Memory* should be taken forward. A key action was the launch of a new independent special health authority, The National Patient Safety Agency (NPSA). Its main aim is to increase the safety of patients by specifically targeting error

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1752-928X/$ – see front matter
doi:10.1016/j.jflm.2012.04.007

reduction. The National Reporting and Learning System (NRLS) was developed by the NPSA in 2004. It collects and analyses information on adverse events at a national level. The NRLS is receiving about 60,000 reports per month.[5] Importantly, the NPSA decided that the reporting system should be voluntary. The NPSA considered a mandatory reporting model but in the end opted for a voluntary reporting system.[6] It was hoped staff would be less fearful of any reprisals by opting for a voluntary system. Recent data from the NPSA has highlighted the success of this system with a decrease in medical errors which resulted in death and an increase in the number of incidents being reported. Comparing the years 2008 and 2009, the number of incidents that resulted in serious patient harm fell from 3643 to 2412 and the number of reported incidents increased from 379,345 to 473,162.[7]

Both reports *An Organisation with a Memory* and *To Err is Human* have been instrumental worldwide in galvanising countries to prioritise patient safety in their healthcare processes. Since the release of *An Organisation with a Memory* improvements in patient safety have been made. There have been no further cases of patients dying from the maladministration of spinal injections. However, at least 22% of incidents are going unreported.[1] Medication errors and, more worryingly, incidents that have led to serious harm or death are less likely to be reported.[1] Doctors especially are disengaged from reporting incidents.[8]

As doctors and medical students, we are taught 'primum non nocere', or 'above all, do no harm' which is of upmost importance in healthcare today. One of the principles of medical ethics is non-maleficence. We must ensure the safety of patients. All healthcare professionals have a duty to act in the best interests of the patient, the principle of beneficence. The General Medical Council has also provided guidance to doctors. The booklet *Good Medical Practice* published in 2006 listed the "duties of a doctor" which contained the obligations of being honest, ensuring you priority is caring for your patients and, importantly, "acting without delay if you believe a colleague may be putting patients at risk".[9] It highlighted that "patients must be able to trust doctors with their lives and health".[9]

Ethically and morally we have a duty to report errors to improve the safety of patient. As of April 2010 in England, Healthcare Trusts have a mandatory requirement to report serious adverse events. The UK Government has taken the view that mandatory reporting of errors is the way forward to improve patient safety in England. Conversely, in Scotland there is no obligatory requirement to report medical errors and although progress is being made, preventable incidents are still taking place.

2. England

On a national level, the National Reporting and Learning System (NRLS) collects and analyses information on adverse events from NHS organisations, staff and even patients or their carers. The NRLS was developed by the National Patient Safety Agency (NPSA) to promote an "open reporting culture and a process for learning from adverse events".[10] There has been a substantial increase in the number of reports the NRLS has received and this is viewed as a positive reflection on healthcare staff adopting a culture of safety. Primary care, before April 2010, had been particularly highlighted as having a very low rate of reporting with only 4% of incident reporting to the NPSA coming from primary care.[11] Due to such under-reporting the Government intervened to implement a requirement for reporting. The Care Quality Commission (Registration) Regulations, made under The Health and Social Care Act 2008 came into force in April 2010. So, from April 2010 all Healthcare Trusts in England were required to mandatorily report to the NPSA 'without delay' all incidents in which patients have suffered serious injury or death.[12] Penalties include a warning notice, £4000 fine or prosecution.[12] The most recent report from the NRLS has demonstrated increased reporting in all healthcare areas with primary care increasing by 10% and a decrease in written NHS complaints, 151,832 in 2009–2010 and 148,171 in 2010–2011. However, litigation costs have also increased which may be multifactorial.

3. Scotland

All Health Boards within Scotland have a voluntary incident and near-miss reporting system in place. Anyone working within NHS Scotland can report an incident on paper or on-line via the DATIX or Safecode system. The incident form is then forwarded to the line manager or the risk management department responsible for collation and added to a database. It is mandatory that all hospitals have systems in place to manage risk.[13] All incident reports are confidential. There is no aggregation of data on a national level.

Health Improvement Scotland, formally, NHS Quality Improvement Scotland (NHS QIS) was launched in 2003 by The Scottish Parliament, and has a responsibility for patient safety in Scotland working with NHS Boards and the NPSA. Incident reporting is part of the Clinical Governance and Risk Management Standards developed by Health Improvement Scotland in 2005. The Scottish Patient Safety Alliance, also co-ordinated by Health Improvement Scotland directly promotes patient safety. When incidents are escalated by risk managers, agencies such as the Health and Safety Executive, Medicine Control Agency, Medicine Devices Agency and The Procurator Fiscal become involved. The most serious adverse events are reported to the Director of Public Health of the relevant NHS Board. There is also an NHS complaints procedure that investigates any patient concerns with independent review being available through the Scottish Public Services Ombudsman (SPSO).

Health Improvement Scotland produced the report *Safe Today – Safer Tomorrow*[8] which highlighted several concerns with current reporting of incidents and near-misses. It concluded that under-reporting is widespread with 82% of doctors surveyed agreeing with this statement.[8] It indicated that near-misses are rarely investigated and any investigations would focus on incidents that "looked likely to result in a claim".[8] 64% of doctors stated that "day to day demands take priority over resolving problems that have to be reported".[8] The personal consequences of reporting an error were raised as a concern by NHS staff. In some cases incident reporting had resulted in disciplinary action.[8] This conflicts with the objective of a 'no blame culture'. Only a few Health Boards provided feedback to the incident reporter and the report itself did not include contextual risk factors.[8] Of great concern, in primary care, the report found 14% or more of healthcare staff did not report incidents.

A study in Greater Glasgow of General Practitioners (GPs) discovered some reasons for such under-reporting. Interestingly, there was some confusion particularly amongst less experienced GPs, as to what constituted a serious event or error and when to report. There were concerns regarding high workload deterring reporting especially within single-handed GP Practices. The study also highlighted that only a minority of GPs would be in favour of a mandatory reporting system. The majority thought it may be "too threatening" and with such a system they would "be selective in the types of error reported".[14] This statement is of great concern since the only way to prevent further serious errors occurring is to report, analyse and learn from previous significant events and near-miss incidents. The study in Glasgow was a small study of 466 GPs, and, it appears that only certain incidents are being reported. The NPSA has recently stated that GPs are "only likely to report incidents that have resulted in severe harm or death".[15]

Significantly, evidence has demonstrated that very serious adverse incidents happen repeatedly over a number of years.[3] Errors fall into patterns which are recurrent, and very often it is an error in the system rather than an individual human error. "The same set of circumstances can provoke similar mistakes regardless of the people involved".[3] Many patients as a result of medical error suffer pain and disability.[3] This is compounded by psychological trauma experienced by patients, their relatives and healthcare staff. In Scotland, patient groups such as the AvMA (Action against Medical Accidents) have seen voluntary reporting of errors as ineffective and are campaigning for mandatory reporting.

4. Culture

4.1. Medical practice culture

Medical practice culture itself has been highlighted as a specific deterrent to any reporting system, voluntary or mandatory.[14]

In medical practice there is an emphasis on perfection and making mistakes is deemed unacceptable. Healthcare professionals view error as a reflection on their character and their medical ability.

Doctors have a genuine reluctance to report errors due to fear of embarrassment and criticism from peers and other colleagues.[16] Loss of reputation, and peer disapproval have been shown to be powerful disincentives to reporting incidents.[17] "Doctors seldom disclose their mistakes to colleagues, family and friends".[18] They often have feelings of shame and guilt. This can affect their self-confidence and ability to practise medicine.

Doctors have an ethical and professional responsibility to be "honest and open" with patients.[9] Patients have the right to know about medical errors even if they have not been harmed. This is based on a patient's right to autonomy. Deceiving patients undermines their ability to make educated decisions as the information that they have been given is incorrect. Patients are also entitled to "make rational choices based on their own beliefs and values".[19] The GMC recommends that doctors make a prompt apology to patients and give a full explanation of what has happened stating any short or long-term consequences.[9] It also advises if a patient has suffered any harm doctors should "act immediately to put matters right".[9] If errors are not reported and patients not informed then this is a breach of medical ethics. Medical errors harm patients, undermine public trust, and destroy the patient doctor relationship.

Encouraging a culture of candour would strengthen the trust between patients and doctors and leave behind the paternalistic culture of 'doctor knows best'.[20]

4.2. Organisational culture

An organisational culture in the NHS can discourage reporting of errors, especially when these incidents are a result of colleague's actions. There is a genuine fear of being labelled a troublemaker, being victimised or disciplined all of which are powerful disincentives to report errors. The Public Interest Disclosure Act 1998, which is applicable in Scotland, was introduced to provide protection to 'whistleblowers' and encourage reporting of errors. "The Act provides statutory protection to employees who disclose information responsibly in the public interest".[3] Recently, this has come under intense public scrutiny as whistleblowers are "still facing 'trumped up' allegations of misconduct, improper behaviour or mental illness".[21]

Within the aviation industry there is an immunity policy which safeguards against disciplinary action for the reporter and this has been seen to be a positive incentive for reporting. *The Public Interest Disclosure Act 1998* was introduced to provide such immunity however adverse publicity has highlighted further incidents in which healthcare staff have faced disciplinary procedures for reporting errors.

To enhance a safety culture in the NHS a move away from a 'blame culture' to an 'informed culture' was recommended. Such an 'informed culture' has four essential components consisting of reporting, just, flexible and learning cultures. A reporting culture would create "an organisation in which people would be prepared to report their errors". In a just culture healthcare staff would have the understanding that only if they were negligent they would be held accountable. An organisation which implements changes in response to error analysis would have a learning culture. A flexible culture is one which "respects the skills and abilities of frontline staff and which allows control to pass to the task expert on the spot".[4]

Unfortunately, within the NHS healthcare staff still feel a 'blame culture' predominates. Doctors and nurses surveyed in Scotland felt that management "was more interested in blame than solutions" and they also felt that "job security could be jeopardised" by reporting.[8] One study found that 55% of doctors and the majority of the public blamed individual healthcare staff for serious medical errors.[22] The report on Lisa Norris' death after a massive overdose of radiation, focussed blame on individuals with very little emphasis on management failures or overall responsibility.[23] Such blame will deter any reporting of errors. The only way to reduce errors is to determine how and why they occur and identify actions to reduce them.

Errors are frequently a result of system failure. The report *To Err is Human* highlighted this by saying,

"Preventing errors and improving safety for patients requires a systems approach in order to modify the conditions that contribute to errors. People working in healthcare are among the most educated dedicated workforce in any industry. The problem is not bad people, the problem is that the system needs to be safer".[2]

In order to make the system safer, cultural changes need to be made. There requires a commitment on an organisational and personal level to be open about errors and this will encourage error reporting and analysis. Healthcare staff must also feel safe when they report an error but, unfortunately, many indeed fear litigation and accountability.

5. Litigation and accountability

The fear of litigation or disciplinary action has been quoted frequently as one of the primary reasons why healthcare staff do not report errors in both voluntary and mandatory reporting systems.[2] Currently, the NHS is said to be facing a malpractice crisis, with an increased number of claims, increased compensation costs and doctors unfairly accused of negligence.[24] The additional cost of significant errors has recently been studied at Aberdeen Royal Infirmary. In this study it was calculated that an adverse event resulted in an average of 7.5 extra bed days. This annual cost of £69,189 was extrapolated to the rest of Scotland with an estimated annual cost £297 million.[25]

The Public Interest Disclosure Act may protect healthcare staff from reprisals on disclosing errors, however it does not protect against malpractice if the whistleblower themselves is the one accountable. Doctors and hospitals have a genuine fear that error reporting may damage their career, reputations and result in malpractice liability. Patients have the right to take legal action if they have been harmed. It is well established principle that patients may litigate through the system of delict. They also have the ethical right to be told about any adverse event, even if they have not been

physically harmed by the incident. Doctors do need to be accountable if their actions are clinically negligent, reckless or indeed criminal. Doctors in Scotland are already one of the most accountable professions as they are faced with multiple jeopardy through the NHS complaints procedure, independent review by the ombudsman, GMC referral, a Fatal Accident Inquiry, criminal proceedings for culpable homicide with all of these potentially running concurrently albeit in reality the processes will run sequentially.

The fear of litigation with error reporting is not evidence based.[26] This has been emphasised by several healthcare organisations reporting a decrease in malpractice litigation after "the implementation of aggressive disclosure policies".[27] If doctors withhold or deceive patients this is more likely to destroy the doctor patient relationship and lead to an initiation of the complaint process. Patients who initiated legal action were surveyed on their reasons for such a course of action. In one study patients commented that they "just wanted greater honesty, an appreciation of the severity of the trauma they had suffered, and assurances that lessons had been learned from their experiences".[28]

There is still significant fear among healthcare professionals even when it is recognised "that error alone does not equal misconduct".[24] One proposal to move forward with the issue of litigation in the NHS is to operate a no fault compensation scheme. This would separate the issue of patient compensation and the issue of assigning blame to the doctor. Campaigners against such a 'no fault' initiative claim that there might be a decline in healthcare standards. To avoid this occurring, any medical errors must be thoroughly investigated.[24]

6. Voluntary reporting

Supporters of voluntary reporting criticise mandatory systems highlighting fears of increased litigation and disciplinary action all deterring reporting leading to a bigger under-reporting issue. Critics have also highlighted that mandatory reporting may also "frighten the public unnecessarily" as the data might not be "valid or complete".[29] GPs surveyed in Scotland found the idea of mandatory reporting "threatening" and commented that in such a system they would be selective about what they reported which would be detrimental to improving patient safety and the learning concept of error reporting.[14]

Doctors have a particular responsibility as there is a professional requirement from the GMC to consider the safety of patients as their first priority and be open and honest with them. As part of the revalidation initiative doctors have to provide evidence to the GMC that they have learned from adverse incident reporting otherwise they will not be fit to practise.

Campaigners for voluntary reporting highlight that ethically and professionally doctors do not need a mandatory obligation to report errors. "Voluntary systems invite a professional ethic of participation in continuous learning and prevention, encouraged by acknowledgement and the reward of visible change".[10] Voluntary reporting of errors is also becoming enshrined in medical education as a move towards a culture of safety. Obligatory reporting may well destroy the patient–doctor relationship as doctors fear litigation and start to practice defensive medicine.

7. Mandatory reporting

Doctors have an ethical responsibility to care for their patients, and this must involve a commitment to report medical errors. Mandatory reporting systems for example in Denmark have seen a high reporting rate with at least 50% of reports coming from doctors and this compares dramatically to percentages for doctors reporting being as low as 1% in Australia where the system is voluntary.[30] England has changed from a voluntary reporting system to a mandatory system to increase the database, monitor performance and intervene quickly with any patient safety issue. Martin Fletcher the Chief Executive of the NPSA recently commented that the move from a voluntary reporting system to a mandatory system in England would "further strengthen patient safety across the NHS".[12] The two reports *To Err is Human* and *An Organisation with a Memory* were instrumental in placing patient safety high on the agenda in worldwide health organisations. Both reports recommended the implementation of a mandatory reporting system for serious adverse events. This was to ensure organisational accountability and a requirement to improve safety systems and patient transparency.[3]

8. Conclusion

Medical ethics encompasses the principles of beneficence and non-maleficence. To prevent harm and act in the best interests of patients, errors must be reported, investigated and new safety procedures implemented. However, the current voluntary system of reporting in Scotland relies entirely on this professional and ethical integrity where it has been demonstrated in many studies to be hindered by cultural issues along with unfounded fears. Evidence has underlined that medication errors and more significantly serious adverse events are not being reported in Scotland. Recently conducted surveys of the organisational culture in NHS Scotland have indicated issues such as heavy workloads, poor feedback and lack of effectiveness of current reporting systems deterring voluntary reporting. Healthcare staff have stated that the actual reporting process is just "an exercise in bureaucracy", with little feedback and only errors that might result in liability being investigated.[8] Incredibly, the NPSA has provided statistical data that in primary care, where most patients are seen, there is the lowest rate of reporting.

A doctor's natural reaction might be to hide or rationalise an error as part of the whole medical culture. Indeed, many leading consultants have recounted stories in which this is the reality of the healthcare profession today. Often patients feel further trauma after a medical error as the whole process is not dealt with sensitively or they are not informed and patient care is further jeopardised. Healthcare staff stated in NHS surveys that they are still fearful of reprisals with a voluntary system of reporting. Newspapers have provided headline news that nurses and doctors still face disciplinary action for reporting errors. The Public Interest Disclosure Act 1998 was introduced to provide immunity for healthcare staff. However this has come under recent scrutiny. Immunity is provided in other reporting systems such as the aviation industry and has increased reporting. Healthcare organisations could also incorporate these criteria. Providing immunity for reporters in a mandatory system avoids a 'blame culture' and the issue of 'whistle-blowing'.

A mandatory system holds Health Boards accountable to report errors, not healthcare staff. Mandatory reporting ensures accountability on a systems basis rather than an individual basis. One benefit is a change from a blame culture to a learning culture. The concept that caring for patients is not an individual responsibility but a team responsibility is reinforced. Adverse incidents should be viewed as flaws in the system not a consequence of an individual human error.

Fears of increased litigation with mandatory reporting are unfounded and disclosing information to the public has been seen in fact to reduce clinical negligence liability claims. Many patients have stated that they simply wanted an apology and assurances

that steps will be taken so that the same error does not happen to another patient and when this did not happen they then initiated litigation. The instigation of an open disclosure policy with a mandatory system demonstrates transparency to patients. Ethically, this would also ensure a patient's right to autonomy is respected as they can see the performance indicators of their local hospital. The duties of a doctor of being open and honest with patients are also fulfilled. Patient charities have stated publically that they wish an open disclosure policy and they want a mandatory system of reporting serious adverse events. An open disclosure policy also has the added benefit of public demand quickly addressing issues such as staff shortages that can increase error occurrence.

Scotland has seen adverse medical errors reported in the media, patients and the public need to regain trust in the NHS. Reading newspaper articles and patient charity reports is heartbreaking especially when the same serious errors are happening time after time and are preventable. The NHS must learn from its mistakes so errors and tragedy do not recur. The evidence that a mandatory system increases the reporting of serious adverse events has already been demonstrated in other countries such as Denmark. Reporting nationally to the NPSA would increase their database and this would allow better analysis of infrequent serious events along with improved monitoring of medication adverse events. Nationally there is no sharing of information in Scotland with the result that Health Boards are not learning from each other. The concept of being 'an organisation with a memory' is therefore failing in Scotland.

The initiation of a mandatory reporting system for serious adverse events and a voluntary reporting of near-miss events would demonstrate Scotland's commitment to improved patient safety.

Ethical approval
None declared.

Funding
None declared.

Conflict of interest
No conflicting interest to declare.

Acknowledgements

My thanks to Dr Rob Hendry and Dr George Fernie from the MPS and to Dr Peter Nelson from St Andrews University for all their helpful comments and assistance. Appreciation should also be given to Peter Walsh, the Chief Executive of AvMA, for giving me insight into a patient's perspective on the effects of medical errors and the ultimate importance of reporting.

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